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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/284,199	08/02/1994	MICHAEL M. BURRELL	1130261CONT.	4511

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EXAMINER

FOX, DAVID T

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 12/02/2002

Rg

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/284,199

Applicant(s)

Burrell

Examiner

FOX

Group Art Unit

1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE - 3 - MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

9/25/02

- ☒ Responsive to communication(s) filed on _____
- ☒ This action is FINAL
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 60-96 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 60-96 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☒ received in Application No. (Series Code/Serial Number) 07/628,216
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

Art Unit: 1638

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment of 25 September 2002 has obviated the rejection under 35 USC 102(g).

Claims 60-96 (newly submitted) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 60, 66, 68, 81, 90, 92-93 and 95-96 are indefinite in their recitation of "promoter...expression in a plant operably linked to" as it is unclear whether the plant or the promoter is operably linked to the subsequently recited claim elements. If the latter were intended, amendment of the claims to insert -- , said promoter-- before "operably" would obviate this rejection. Dependent claims are included in the rejection.

Claims 68-96 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a method of transforming plants with a chimeric gene comprising nucleotide sequences encoding pyruvate kinase, acid invertase, starch synthase, 6-phosphofructokinase (pyrophosphate), sucrose synthase and sucrose phosphate synthetase from any source and of any sequence. In contrast, the specification and the Burrell declaration filed 25 March 1993 in parent application Serial No. 07/991,451 only provide guidance for the isolation of

Art Unit: 1638

the phosphofructokinase and ADP glucose pyrophosphorylase genes, and plant transformation therewith. No guidance has been provided for the isolation or characterization of any of the newly claimed enzymes from any source, or for the isolation and characterization of their corresponding genes.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately

Art Unit: 1638

described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111).

Claims 62, 77 and 95 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to transformed potato plants which produce tubers, does not reasonably provide enablement for any tuber from any plant species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to any plant species encompassing physiologically and morphologically divergent plant species such as grasses, corn, palm trees, tobacco, apple, soybean, pine, squash, etc, and tubers produced therefrom, wherein none of these plants in fact produces a tuber. The specification only provides guidance for tubers produced from potatoes.

Given the morphological limitations of the majority of broadly claimed plant species, and the lack of guidance in the specification for altering said limitations, it is unlikely that one skilled in the art would have been able to produce tubers on a multitude of non-exemplified plants, and undue experimentation would have been required by one skilled in the art to attempt such an endeavor.

Art Unit: 1638

Claims 68-96 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to a method of transforming plants with a chimeric gene comprising nucleotide sequences encoding pyruvate kinase, acid invertase, starch synthase, 6-phosphofructokinase (pyrophosphate), sucrose synthase and sucrose phosphate synthetase from any source and of any sequence. In contrast, the specification and the Burrell declaration filed 25 March 1993 in parent application Serial No. 07/991,451 only provide guidance for the isolation of the phosphofructokinase and ADP glucose pyrophosphorylase genes, and plant transformation therewith. No guidance has been provided for the isolation or characterization of any of the newly claimed enzymes from any source, or for the isolation and characterization of their corresponding genes.

Plant transformation with genes encoding other enzymes involved in glycolysis or carbohydrate metabolism is unpredictable. It is unclear whether plant transformation with genes encoding other glycolytic enzymes would alter glycolysis and/or kill the transformed plant cells and plants (see, e. g., page 3 of the specification, first full paragraph; page 3 of the ap Rees declaration filed 22 January 1993 in parent application Serial No. 07/991,451). It is also unclear whether plants transformed with more than one glycolytic gene would be adversely affected, given the "double dose" of glycolytic enzyme alteration.

Art Unit: 1638

Furthermore, von Schaewen et al. demonstrate the unpredictability inherent in the transformation of plants with genes encoding glycolytic enzymes. The transformation of tobacco with an invertase gene resulted in dwarfing, bleaching and browning of leaves, and root stunting (see, e. g., page 3037). The lack of such deleterious effects on plant health in the potato plants transformed with the PFK gene has been previously argued by Applicants as evidence of unexpected results. Respiration, i. e. glycolysis, was also inhibited (see, e. g., page 3039, column 1, bottom paragraph). Furthermore, the transformation of a different plant species by von Schaewen et al. resulted in a completely different response to the introduction of a glycolytic gene, i. e. lack of appreciable change in phenotype or starch content (see, e. g., page 3038, column 1, top paragraph; page 3039, column 2, bottom paragraph).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would be required by one of ordinary skill in the art to identify and isolate the gene or genes which encode any other non-exemplified glycolytic enzyme, and to evaluate the effects of said gene(s) on a multitude of non-exemplified transformed plant cells and plants.

Claims 60-96 are deemed free of the prior art, in view of the unpredictability inherent in the expression of glycolytic genes in whole plants as discussed supra, the failure of the prior art to teach or reasonably suggest plant transformation with said glycolytic genes, and further in view of the demonstration by Applicant that the transformation of potato plants with the exemplified phosphofructokinase or ADPGPP genes exhibited desirable levels of starch accumulation without deleterious effects on plant health, as stated in allowed parent application Serial No. 07/991,451.

Art Unit: 1638

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

November 27, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638

